

**When do proposed changes warrant a modification or amendment request versus a new IRB application?**

When proposing changes to an existing approved protocol, it is important to consider whether the changes may warrant submission of a new protocol rather than a modification/amendment. It is a misconception that modification or amendment requests are easier and faster than submitting a new application. Xavier's IRB must examine any modification/amendment using the same standards for review and approval as any other submission. A modification or amendment that does not adequately explain changes, includes inconsistencies, or does not provide the appropriately revised materials will slow the review process and result in follow-up communications with the IRB. In some cases, a new application is easier to develop, review and approve.

When deciding whether to submit a modification/amendment or a new protocol, consider the following:

1.	<p><i>Do the proposed changes alter the research hypotheses? Is there a change in the study purpose and/or aims?</i></p> <ul style="list-style-type: none"> <li>• If the basic research question or purpose remains intact, then a new application may not be warranted.</li> <li>• If the research question has changed, even if it builds on the knowledge learned from a prior approved protocol, then a new application may be warranted.</li> </ul>
2.	<p><i>How will the procedures/methods change?</i></p> <ul style="list-style-type: none"> <li>• If the procedures/methods to be used remain essentially the same, then a new application may not be warranted. <ul style="list-style-type: none"> <li>○ For example, if the <i>only</i> changes involve substituting one questionnaire with another <i>similar</i> questionnaire or adding different stimuli of the <i>same</i> type, then submitting a modification/amendment may be appropriate.</li> </ul> </li> <li>• If the new procedures/methods deviate from the original approved protocol, then a new application may be warranted. <ul style="list-style-type: none"> <li>○ If the changes to the procedures/methods result in a study that is different (e.g., asks a different research question) from the approved protocol, modifications/amendments can affect the quality of review and may not be appropriate. Submitting a new study may be necessary.</li> </ul> </li> </ul>
3.	<p><i>How long ago was approval obtained?</i></p> <ul style="list-style-type: none"> <li>• If the approved protocol reflects a longitudinal study and if changes are otherwise closely related to the previously approved protocol (see item #2), then submitting an amendment may be appropriate.</li> <li>• If the approved protocol is not intended as longitudinal research and was approved in previous academic years, a new application may be appropriate.</li> </ul>
4.	<p><i>When might a modification or amendment really be a new IRB application?</i></p> <p>If the modification or amendment includes changes to two or more of the following criteria, the IRB would likely consider it to be a new study and the investigator(s) would be asked to submit a new protocol.</p> <ul style="list-style-type: none"> <li>• Study population</li> <li>• Study procedures</li> <li>• Study purpose</li> </ul> <p>[This guidance also applies when modifications/amendments are submitted to the same approved protocol successively across time.]</p>